ISRCTN88921195 https://doi.org/10.1186/ISRCTN88921195

Wearable device to Observe Movements of your Baby (WOMB) study

Submission date 28/04/2021	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/07/2021	**Overall study status** Ongoing	
Last Edited 12/09/2024	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
Fetal movements are reassuring for fetal health. It can be difficult for some women to appreciate fetal movements and this can lead to unnecessary medical intervention. We propose to test a thin, flexible textile-like sensor (which is conformable, breathable, and washable) embedded within a wearable garment, KYMIRA will create a solution that is easier and more comfortable for longer-term monitoring. Moreover, the wearable will be fully washable, enabling better hygiene and potentially allowing 24-hour monitoring.

We aim to correlate objectively measured fetal movements with those detected by the device via real-time imaging of the moving fetus using ultrasound. The study intervention will involve four ultrasound scans lasting 20 min during which fetal movements will be recorded by the scan operator. The fabric device will also be worn on the mother's abdomen and will also be recording movement. The mother will also have a button to press when she feels movements. The four scans will happen at 2-week intervals from 32 weeks of pregnancy.

Other studies have looked into various devices. Often these are bulky, non-washable and require hospital visits. Some use methods, such as picking up the acoustics of fetal movement. Our device works by using a piezoelectric fabric which essentially generates a tiny voltage when the material is bent or stretched.

Who can participate?
Women aged 18-40 who are pregnant with one baby and have a body mass index (BMI) between 18-30.

What does the study involve?
Participants will be asked to attend 4 extra ultrasound scans in the later part of their pregnancy. A fabric device will be worn which is designed to pick up movements of the fetus. Both the mother, the device, and the scan operator will be assessing fetal movements.

What are the possible risks and benefits?
Taking part in the trial is not going to be directly beneficial to participants, although they will get to see their baby on scan a few extra times. The disadvantage of taking part in the trial is that

participants will be asked to come into the hospital for four extra scans between 32 and 38 weeks of pregnancy. This will take time out of their day.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust (UK) and University Hospitals of Leicester (UK)

When is the study starting and how long is it expected to run for?
From June 2021 to December 2025

Who is funding the study?
Kymira (UK) through an Innovate UK grant

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2021-002341-15

IRAS number
288119

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
WOMB01, IRAS 288119

Study information

Scientific Title
Wearable device to Observe Movements of your Baby (WOMB) study

Acronym
WOMB

Study objectives
To determine the effectiveness of the wearable device in detecting fetal movements, as identified by the operator scanning, compared with those detected by the pregnant women.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/04/2023, Health and Social Care Research Ethics Committee A (HSC REC A) (ORECNI, Lissure Industrial Estate West, 5 Rathdown Walk, Lisburn, BT282RF, United Kingdom; +44 (0)28 9536 1400; RECA@hscni.net), ref: 21/NI/0115

Study design
Multicentre single-arm non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
The participant information sheet is not yet available.

Health condition(s) or problem(s) studied
Fetal movement

Interventions
Pregnant women in their third trimester with a singleton pregnancy will test a device designed to pick up fetal movements. The WOMB device will be worn for 20 min by the pregnant participant in the third trimester during ultrasound scans at weeks 32, 34, 36, and 38 of pregnancy. A scan operator and the mother will also be determining when the fetus is moving. The results will then be correlated with what the wearable device has picked up.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fabric device

Primary outcome measure
Effectiveness of the wearable device in detecting fetal movements, as identified by the operator scanning, compared with those detected by the pregnant women measured using data from the wearable device, ultrasound scan, and maternal report during the 20 min scan at weeks 32, 34, 36, and 38 of pregnancy

Secondary outcome measures
1. Proportion of movements detected by the device and by the pregnant women that are true-positives, that is those that are also identified by the scan operator (i.e., their positive-predictive value rates) measured using data from the wearable device, ultrasound scan, and maternal report during the 20 min scan at weeks 32, 34, 36, and 38 of pregnancy
2. Acceptability of wearing the device as self-reported by the women in a bespoke end of study questionnaire

Overall study start date
01/01/2020

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the study
2. Aged between 18 and 40 years
3. ≤32 weeks gestation
4. Body mass index (BMI) between 18 and 30 at booking
5. Able (in the Investigator's opinion) and willing to comply with all study requirements
6. Willing to allow their General Practitioner and Obstetric Consultant, to be notified of participation in the study
7. Singleton pregnancy

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
54

Key exclusion criteria
1. Any concerns have been raised at previous scans, although if the scan has been reviewed by fetal medicine and deemed there are no concerns then the patient can be included
2. Delivery planned prior to 39 weeks at recruitment.
3. Multiple pregnancy

Date of first enrolment
01/10/2024

Date of final enrolment
01/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridge University NHS Foundation Trust
Robinson Way
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
University Hospitals of Leicester
Infirmary Square
Leicester
United Kingdom
LE15WW

Sponsor information

Organisation
Kymira

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Kymira

Results and Publications

Publication and dissemination plan
Planned publication in high impact peer reviewed journals.

Intention to publish date
01/03/2026

Individual participant data (IPD) sharing plan
Data collected from the device that is worn by participants will be kept by Kymira and are not expected to be made available. The analysed data collected during this study will be included in the subsequent results publication.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	version 1				

Participant information sheet	version 2	12/05/2016	27/07/2021	No	Yes
Protocol file		12/04/2021	27/07/2021	No	No